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10/524,130	10/14/2005	Tina Bruce	088212-010701	2464

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EXAMINER

STEPHENS, JACQUELINE F

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3761

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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/524,130	Applicant(s) BRUCE ET AL.	
	Examiner Jacqueline F. Stephens	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-37 and 39-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-37, 39-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 10/22/10 have been fully considered and they are moot in light of the new rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 26-27, and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Furuno et al '195 as evidenced by Farrell '672.

Claim 26: See the Figures, the abstract, col. 1, lines 20-23, 26-29, and 52 -63, col. 2, lines 7-13, and 24-65 and col. 3, lines 16-18 and claims, i.e. '195 teaches a re-useable nipple cover sized and shaped to cover the nipple comprising a body 1, see also discussion infra, with an inner layer 3 that is adapted to contact the nipple and has a thickness of between 10 and 20 mils, see, e.g., col. 4, lines 16-17 and col. 1, lines 57-58, i.e. greater than 8 mils, and MPEP 2131.03, with "sufficient specificity". Furono provides the general condition an outer layer 2 secured to an outer surface of the inner layer, the body having a total thickness of 20-90 mils, i.e. .02 to .09 inches or .5 to 2.25 mm, see, e.g., again col. 4, lines 16-17 and col. 1, lines 57-58, i.e. greater than 8 mils,

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and MPEP 2131.03, with “sufficient specificity”, e.g. outer layer can have thickness 8-24 mils and inner layer is thicker than outer layer, e.g. total body thickness is greater than 16 mils. Claim 26 further requires 1) the body be silicone rubber , and 2) the body be a reusable breast shield sized to cover a nipple, areola, and surrounding breast area of a human female with an inner layer that contacts against the nipple, areola, and surrounding breast area, i.e. a property, function or capability of the claimed structure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the layers with the claimed thickness since where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation, In re Aller et al. 105 USPQ 233.

With regard to 1), see, e.g., col. 1, lines 54-55 with regard to the outer layer and col. 2, lines 36-45, esp. 43-44 as evidenced by ‘672 at col. 15, lines 37-41, i.e. “KE1052(A-B)” is a RTV silicone rubber. With regard to 2), while ‘195 as discussed supra teaches a body which is sized and shaped to cover the nipple and an inner surface which contacts the nipple, it does not appear to explicitly set forth the capability, function or property of the body to further cover the aureola and a portion of surrounding breast area of a human female breast and the inner layer to contact such. However see the discussion of claim 31-32 infra and the Figures, i.e. the same size and shape as claimed. Therefore, at the very least, there is sufficient factual evidence for one to conclude that such body/inner layer of such same size and shape of ‘195 would also

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inherently include the same capability, i.e. coverage of/contact with the aureola and a portion of surrounding breast area of a human female breast. See MPEP 2112.01.

Claim 27: The inner layer is constructed of a first silicone rubber, see, e.g., col. 2, lines 34-45, a “gel”, and the outer layer is constructed of a different second silicone rubber, see col. 2, lines 7-11.

Claim 30: The inner layer includes a smooth inner surface that contacts against the nipple, areola, and surrounding breast area, see, e.g., the discussion of claim 1 and the Figures of ‘195.

Claim 31: The shield has an elliptical curvature, see, e.g. Figures of ‘195.

4. Claims 28, 33-34, 36, 37, 39-42 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Furuno et al ‘195 as evidenced by Farrell ‘672, the instant application at page 7, lines 7-8, Ikeno ‘890 and Muramatsu et al ‘581.

Claim 33: See discussion of claims 26-27 and 30-31 supra. This claim also requires the first layer have a durometer of 10 or less Shore A and the second layer has a durometer of between 0 and 100 Shore A. ‘195 as evidenced by ‘672 teaches a first/inner layer 3 which comprises a silicone rubber “gel” compound and such “gel” has a stiffness of less than 10 durometer Shore “A”, i.e. 0 durometer Shore “A”, with “sufficient specificity”, note again MPEP 2131.03, as evidenced by page 7, lines 7-8 of the instant application, ‘890 at col. 2, lines 62-65 and ‘581 at col. 2, lines 18-22, and ‘195 teaches a second/outer layer 2 of silicone rubber, see col. 2, lines 7-12, i.e. not a “gel”, i.e. greater than 0 durometer Shore “A”, which has a stiffness of between 0 and

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100 or less durometer Shore "A" with "sufficient specificity", note again MPEP 2131.03, as evidenced by page 7, lines 7-8 of the instant application, '890 at col. 2, line 62-col. 3, line 6 and '581 at col. 2, lines 18-26. Note also paragraph 13 infra.

Claims 28, 34, 41: See the discussion of claim 33, i.e. the second/outer rubber layer includes a greater durometer than the first/inner gel layer.

Claims 36, 37, 39, 40, 42 and 44: See discussion of claims supra.

6. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Furuno et al '195.

The shield has a diameter in the range of 1.0 to 5.0 inches, see col. 1, lines 60-63, i.e. the diameter is 1.4 to 2.6 inches. Note again MPEP 2131.03, I. Claim 32 further requires the shield have a depth in the range of between 0.5 to 2.5 inches. While '195 teaches a shield having a depth, see Figures and, e.g., col. 2, lines 7-48, it does not disclose the specific depth range as claimed. It is further noted that the instant specification does not disclose the criticality of such a range of depth as claimed. Still further '195 not only recognizes that such depth, i.e. shape, is a result effect variable, see, e.g., col. 2, lines 7-48 and MPEP 2144.05, but teaches a re-useable curved body shaped to a portion of the breast for covering/shielding the nipple like the disclosed invention. Therefore, since the general conditions of the claim are disclosed by '195, it is not inventive to discover the optimum ranges by routine experimentation, In re Aller, 105 USPQ 233 (CCPA 1955).

11. Claims 29, 35 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Furuno et al '195 as evidenced by Farrell '672, alone or such and the instant application at page 7, lines 7-8, Ikeno '890 and Muramatsu et al '581.

These claims require the inner and outer layers are or body is translucent. While '195 as evidenced by '672 at col. 15, lines 37-41, i.e. "transparent" and col.2, lines 63-65 of '195 teach a transparent inner/first layer and the inner first layer and second outer layer are indistinct at the boundary therebetween, '195 does not explicitly teach the second outer layer being transparent, i.e. translucent. However, to employ a transparent, i.e. translucent, second/outer layer, and thereby transparent body, on the '195 device if not already would be obvious to one of ordinary skill in the art in view of the recognition that such would provide an indistinguishable boundary between the layers and the desire of such by '195. See also paragraph 13 infra.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline F. Stephens whose telephone number is (571) 272-4937. The examiner can normally be reached on Monday-Friday 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline F Stephens/

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Primary Examiner, Art Unit 3761